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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/749,522	01/02/2004	Beka Solomon	SOLOMON=2B.2	9533

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EXAMINER	
BALLARD, KIMBERLY A	
ART UNIT	PAPER NUMBER
1649	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/12/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/749,522	SOLOMON ET AL.	
	Examiner	Art Unit	
	Kimberly A. Ballard	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 January 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11 and 25-34* is/are pending in the application.

4a) Of the above claim(s) *1-6* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *7-11 and 25-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

Claims 1, 7, 25 and 30 have been amended as requested in the response filed January 16, 2007. Claims 1-11 and 25-34 are pending in the instant application.

Claims 1-6 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 13 June 2006.

Claims **7-11** and **25-34** are under examination in the current office action.

Information Disclosure Statement

At page 8 of the response filed January 16, 2007, Applicants note that a new IDS form listing the previously lined-through reference has been attached to the response. However, no such paper is present in the file. Applicants are invited to resubmit this IDS form for consideration.

Maintained Claim Rejections

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The rejection of claims 7-11 and 25-34 under 35 U.S.C. 103(a) is maintained for reasons of record. Claims 7-11 and 25-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Solomon et al. (*Proc Natl Acad Sci USA*, April 1997; **94**: 4109-4112) and Hanan & Solomon (*Amyloid: Int J Exp Clin Invest*, 1996; **3**:130-133, both as evidenced by Frenkel et al. (*J Neuroimmunol*, August 1998; **88**: 85-90), and both in view

of US Patent No. 5,846,533 to Prusiner et al., issued 8 December 1998, filed 13 September 1996, and Pasqualini (*Mol Psychiatry*, 1996; 1: 423).

In the response filed January 16, 2007, Applicants argue that neither Prusiner nor Pasqualini teaches the use of phage displaying any specific antibody as a delivery system, and therefore there would have been no motivation to combine Prusiner and/or Pasqualini with the primary references for any purpose. For example, Applicants note that Prusiner makes it clear that the antibodies displayed in the phage library are removed from the phage before they are therapeutically used, and thus nothing in Prusiner is used as a delivery system. Similarly, Applicants assert that there is no disclosure in Pasqualini that phages containing the random peptide homing sequences are ever used therapeutically, i.e., as a delivery system for the specific peptides that are identified by Pasqualini's process. Applicants evidence Patent No. 5,622,699, in which the inventors are the two authors of the Pasqualini publication and which, Applicants assert, there is no disclosure in the entire patent about therapeutic use of a phage displaying an organ-homing molecule or a delivery system comprising such. As such, Applicants conclude that no combination of the references of record teach or suggest any motivation for administering a specific antibody while displayed on a filamentous bacteriophage.

Applicant's arguments have been fully considered but they are not persuasive. In response to applicant's argument that there is nothing in the combination of references that would teach or suggest the administration of a specific antibody displayed on a filamentous bacteriophage for therapeutic use, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention

and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

Furthermore, the recitation of "a pharmaceutical composition" in claims 7-11 has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

Notwithstanding the above remarks, the motivation for using a antibody displayed on a filamentous bacteriophage for therapy can be found in the teachings of Hanan & Solomon (1996), who clearly state that through advances in antibody engineering techniques and the development of suitable delivery systems, functional small antibody fragments may serve as new therapeutic approaches for the treatment of Alzheimer's disease, as well as other human amyloid diseases (see p. 132, final paragraph). The skilled artisan would therefore be motivated to develop such suitable delivery systems, and would further recognize the teachings of Prusiner and Pasqualini, providing for phages that display antibody fragments or binding peptides capable of functionally binding the desired target antigen.

Finally, the fact that Pasqualini (and the Pasqualini patent 5,622,599) teaches *in vivo* administration of phages displaying homing proteins, which are structurally the

same as the binding fragment region of an antibody (such as an Fab' fragment), evidences that such a combination is a suitable pharmaceutical composition for in vivo administration, and therefore would not be incongruous with either therapeutic or diagnostic use of the composition. Further, Pasqualini teaches a method of selecting for brain-selective phage molecules, and suggests that this method may provide a new means for selective targeting of therapies. Thus, the skilled artisan would have ample motivation to make and use a filamentous bacteriophage displaying an anti-amyloid-β antibody epitope binding fragment, based on Hanan & Solomon's suggestion for developing a suitable antibody fragment delivery system and Pasqualini's teachings that phage-displayed peptides can be targeted to the brain. Whether such a pharmaceutical composition would be used therapeutically or diagnostically or even to monitor the level of amyloid-β protein in the brain to assess the effects of another treatment would therefore all be secondary to the fact that the combination is pharmaceutically acceptable, but nonetheless would be reasons to for the skilled artisan to make such a combination, thus rendering the instant invention obvious at the time of filing.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kimberly A. Ballard whose telephone number is 571-272-4479. The examiner can normally be reached on Monday-Friday 9AM - 5:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on 571-272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Elizabeth C. Kemmerer

Kimberly Ballard, Ph.D.
March 30, 2007

ELIZABETH C. KEMMERER, PH.D.
PRIMARY EXAMINER